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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TSAY, MARSHA M

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,496

Applicant(s)

LEMANSKI ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

This Office Action is in response to Applicants' remarks received November 23, 2005. Claims 1-24 are pending. Claims 5, 15-24 are withdrawn. Claims 1-4, 6-14 are currently under examination.

Priority date is April 10, 2003.

Withdrawal of Objections and Rejections

The rejection of claims 1-14 under 35 U.S.C. 101 is withdrawn.

The rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, is withdrawn.

The objection to the disclosure, specifically the brief description of drawings, because of minor informalities is withdrawn.

The objection to claims 1, 7, 10, 13 because of minor informalities over notation is withdrawn.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Lemanski et al. (1996 Biochem. Biophys. Res. Comm. 229: 974-981; IDS) is withdrawn.

Maintenance of Objections and Rejections/New Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected again under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 7, 10, 13 are drawn to a purified nucleic acid comprising a purified nucleic acid comprising a nucleotide sequence that encodes a MIR molecule. As disclosed in the instant invention, a MIR molecule is a RNA molecule. It is known in the art, that the term "encodes" is used in the sense that DNA encodes protein. Since the instant claim is drawn to RNA and not protein, it is suggested that another term be used to describe the transcription of the DNA to RNA. A possible suggestion is: A purified nucleic acid comprising a nucleotide sequence that is transcribed into a myofibrillogenesis-inducing RNA (MIR) molecule. Additionally, RNA does not have "functional activity" per se, so it is unclear what the activity of RNA is.

Claims 4, 6, 8-9, 11-12, 14 are included in this rejection because they are dependent on the above claims.

Claim 7 recites "shares sequence identity" in the claim. The claim is indefinite because it is unclear what "shares sequence identity" means. The claim can be interpreted to mean any level of shared identity, for example, from 1% to 99%.

Claim 10 recites said deoxyribonucleic acid sequence encodes a polyribonucleic acid as identified by SEQ ID NO: 5. SEQ ID NO: 5 has already been identified as depicting a nucleic acid sequence, as recited in instant claim 1. Therefore, it is unclear what type of sequence is recited or represented in Claim 10.

In their remarks received November 23, 2005, Applicants disclose on page 11 that the claims have been amended to correct for the term "encodes." However, the current claims do not reflect a change regarding the use of the term "encodes." Therefore, the rejection of claims 1-3, 7, 10, and 13 under 35 U.S.C. 112, second paragraph, is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-14 are rejected again under 35 U.S.C. 103(a) as being unpatentable over Lemanski et al. (1996 Biochem. Biophys. Res. Comm. 229: 974-981; IDS). Lemanski et al. teach the construction of a cDNA library in a pcDNAII vector with T7 and Sp6 polymerase promoters. Synthetic RNA was prepared *in vitro* by T7 RNA polymerase and found to be active in rescuing mutant hearts as determined by their initiating contractions and forming organized myofibrils containing tropomyosin. Lemanski et al. teach an active and unique clone (Cl#4), depicted in Fig. 1, that is transcribed into a MIR molecule having at least one functional activity of a native MIR molecule. Lemanski et al. do not teach a nucleic acid as identified by SEQ ID NO: 5.

It would have been obvious to a person having ordinary skill in the art to construct a vector, such as pcDNAII, comprising a purified nucleic acid that transcribes a MIR molecule having at least one functional activity of a native MIR molecule because

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Lemanski et al. teach the construction of a vector comprising a polynucleotide sequence that is used to prepare a homologous myofibrillogenesis-inducing RNA (MIR) molecule and further encodes a MIR-binding protein.

Applicants traverse the rejection of claims 13-14 under 35 U.S.C 103(a) as being unpatentable over Lemanski et al. because SEQ ID NO: 5 is recited in instant claim 13 and Lemanski et al. do not teach the nucleic acid depicted as SEQ ID NO: 5. However, as explained in the 103(a) rejection above, Lemanski et al. do teach a nucleotide sequence of Cl#4 that is transcribed into a MIR molecule having the functional activity of a native MIR molecule. The nucleotide sequence of Cl#4 corresponds to nucleotides 312-475 of instant SEQ ID NO: 5. Lemanski et al. teach the RNA from Cl#4 is capable of promoting myofibrillogenesis (p. 976). Therefore, despite the length of the nucleic acid, the nucleotide sequence of Lemanski et al. still transcribes into a RNA molecule that has the same functional activity of a native MIR molecule as disclosed in the instant invention.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER